REMARKS

Claims 33-37 are pending in this application. Claims 33, 34 and 37 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,731,079 issued to Stoy (hereinafter "Stoy"). Claim 35 stands rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over Stoy. Finally, claim 36 is rejected under 35 U.S.C. § 103(a) as being obvious over Stoy. Applicant traverses these rejections for at least the following reasons.

Applicant respectfully submits that the claims of the present invention are not anticipated or rendered obvious in light of the Stoy patent, as the Stoy patent fails to teach or suggest all of the limitations of the present claims.

Claim 33 is the sole independent claim of the application, with claims 34-37 depending directly or indirectly on claim 33, and therefore containing all of the limitations of claim 33.

Claim 33 reads as follows:

> "A method of manufacturing an intraocular lens, the method comprising:
> a) providing a rigid, hydratable copolymer comprising
> a first monomeric component which comprises an aryl acrylate or an aryl methacrylate;
> a second monomeric component which comprises a monomer having an aromatic ring with a substituent having at least one site of ethylenic unsaturation, wherein the second monomeric component is other than an acrylate; and
> a third monomeric component <u>which comprises a high water content hydrogel-forming monomer</u>,
> wherein the copolymer has a glass transition temperature greater than about normal room temperature;
> b) forming a rigid intraocular lens having the desired dimensions from the rigid copolymer; and
> c) hydrating the copolymer to form a foldable, hydrated intraocular lens,
>
> wherein the hydrated intraocular lens has an equilibrium water concentration less than about 10 weight percent, and a refractive index greater than about 1.55" (see claim 33, emphasis added).

The specification of the application discloses that high water content hydrogel forming monomers are:

> "Materials [which] are hard or rigid when dry, and absorb a large amount of water (*e.g.* up to 20%-70% by weight) when hydrated, which lowers the refractive index of the material" (see page 1, line 27 of the specification).

Specific examples of such materials are set forth in Example 1 of the application.

In response to the previous Office Action (Amendment mailed 2/19/03), Applicant pointed out that the Stoy reference failed to disclose a third monomeric component which comprises a high water content hydrogel-forming monomer" (see claim 33, emphasis added). Applicant noted that the Office Action erroneously equated a cross-linker and a hydrogel in the analysis of the disclosure of Example II of Stoy (Amendment mailed 2/19/03 at page 2).

The present Office Action states that Example II of the Stoy patent discloses:

> "..85 grams of benzyl acrylate, (first monomer of the instant claim 33) 15 grams of styrene (second monomer of the instant claim 33) and 0.35 grams of tetraethyleneglycol-bis-metharylate (third monomer of the instant claim 33)" (see page 2 of Office Action).

Applicant again respectfully submits that tetraethyleneglycol-bis-metharylate (also referred to as tetraethyleneglycol-dimetharylate "TEGDMA") cannot be considered a high water content hydrogel forming monomer as set forth in the present claims. In response to Applicant's arguments in the previous response, the Examiner stated that:

1. "Applicants do not name the high water content hydrogel forming comonomer in [the] claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into claims" (see page 5 of Office Action); and

2. "The references cited in PTOL- 892 [U.S. Patent No. 5,453,530 issued to Byerley et al. (hereinafter "Byerley) and U.S. Patent No. 4,962,170 issued to

Chromecek et al. (hereinafter "Chromecek")] submitted along with this Office Action show that tetraethyleneglycol-bis-metharylate is a hydrogel forming high water content monomer.

As to the Examiner's first point, the limitation of the third monomer being a "high water content hydrogel forming monomer" is not "read into" the claims, but rather is specifically recited in claim 33, on which all the remaining claims depend. Applicant has chosen to claim a constituent of the copolymer used in the method in this manner. As delineated in § 2173.01 of the Manual of Patent Examining Procedure (MPEP):

> "A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art. Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. As noted by the court in In re Swinehart, 439 F.2d 210, 160 USPQ 226 (CCPA 1971), a claim may not be rejected solely because of the type of language used to define the subject matter for which patent protection is sought."

Applicant is under no obligation to claim specific high water content monomers in the application when the scope of the invention is not so limited.

As to the Examiner's second point, Applicant again respectfully submits that tetraethyleneglycol-bis-metharylate cannot be considered a hydrogel forming high water content monomer. This issue is considered at length in the attached Mentak Declaration.

In the Declaration of Dr. Mentak, it is noted:

> "A monomer needs to have certain properties in order to form a hydrogel in a homopolymer state. The monomer needs to have hydrophilic groups capable of binding and retaining water as a solute. More importantly, such moieties need to remain available for water molecules after polymerization. The hydrophilic character of the monomer decides the thermodynamic feasibility of water diffusion and retention by a polymer network. However, hydrophilicity is not sufficient to ensure that a monomer is hydrogel forming. The monomer must also

> allow water diffusion into the polymer network. Water diffusion in crosslinked polymer networks is based on the free volume theory, which postulates that polymer systems demonstrate the presence of void space or unoccupied volume. Free volume is a result of packing irregularities and long-range monomer interactions which give rise to excluded volume effect" (see paragrah 9 of the Mentak Declaration).

Dr. Mentak goes on to note that "The free volume theory postulates that for diffusion to occur, water molecules must jump from one void to the next... Water can diffuse through the gel if it finds a succession of holes larger than the water molecules" (see paragraphs 10 and 11 of the Mentak Declaration). Dr. Mentak points out that:

> "If the polymer network is unusually highly crosslinked water molecules are not able to jump from one void to the next, hence water cannot diffuse into the polymer network. This type of crosslinked polymeric network cannot absorb and hold water and is not hydrogel forming" (see paragraph 12 of the Mentak Declaration).

Dr. Mentak indicates that the crosslink density of a polymer has a powerful effect on the ability of a given hydrogel to hold and retain water. Dr. Mentak notes that:

> "The greater the crosslink density, or concentration of crosslinking agent, the smaller the mesh size of the polymer network and the lower the equilibrium water content (EWC). Polymerizing a crosslinking agent such as TEGDMA alone would create such a tight polymer network that water molecules cannot diffuse into the bulk of the polymer. Such materials cannot absorb or hold water. Because of the hydrophilic nature of the monomer, water may adsorb to the surface of the polymer, but will not diffuse into the bulk of the material. Such polymers do not fit the definition of a hydrogel" (see paragraph 15 of the Mentak Declaration).

The claims of the present invention contain the limitation of the use of a copolymer wherein the third monomeric component comprises a high water content hydrogel-forming monomer. That is, the monomeric component alone, when polymerized, would form a hydrogel. This is not the case with tetraethyleneglycol-bis-metharylate. As indicated by Dr. Mentak,

TEGDMA, when polymerized alone, would create a tight polymer network, and would not be considered a hydrogel forming monomer by one of ordinary skill in the art.

The Examiner has indicated that Byerley in Col. 9, lines 32-40 and Chromecek in Col 3, lines 44-46, teach that TEGDMA is a hydrogel forming monomer. Applicant respectfully submits that this is not the case.

Dr. Mentak notes that:

> "In Byerley, the patent describes the use of TEGDMA in conjunction with thioacrylic and thiomethacrylic acids to form hydogels In this instance, TEGDMA is used as a crosslinking agent the same way it is used with other hydrophilic monomers to form hydrogels. In my opinion, there is nothing in the section highlighted by the examiner that suggests that TEGDMA, polymerized alone or with another crosslinker, can yield a hydrogel" (see paragraph 17 of the Mentak Declaratiion).

Dr. Mentak also notes that:

> "Chromecek teaches a method of making highly adsorptive polymers. The key element of this invention is to create highly crosslinked polymeric particles that retain certain liquids by surface adsorption, but not bulk absorption. A powder with small particle size was preferred for increased surface area and hence enhanced superficial adsorption volume. The particles are not made highly porous to minimize swelling by liquid absorption. More specifically, TEGDMA as monomer was selected for this invention to produce highly crosslinked non-swellable polymers, but with the ability to adsorb water on particle surfaces. This reinforces the point that TEGDMA is not hydrogel forming" (see paragraph 18 of the Mentak Declaration).

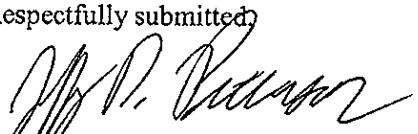
Applicant respectfully submits that tetraethyleneglycol-bis-metharylate is not a hydrogel forming monomer, and therefore cannot be considered to teach or suggest the third component of the claimed copolymer. Applicant respectfully submits that the sole cited reference, Stoy, fails to teach or suggest all of the limitations of the claimed invention. Therefore Stoy fails to

anticipate claims 33-37, and fails to provide a *prima facie* case of obviousness with respect to claim 36.

Applicant respectfully submits that the pending claims of the current application are novel and unobvious over the cited prior art, and are in condition for allowance. Applicant therefore respectfully requests that the pending claims of the application be passed to issue.

Should the Examiner feel that any other point requires consideration or that the form of the claims can be improved, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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